Chapter 1

Introduction

1.1 Background and Overview

Within the U.S. Environmental Protection Agency (EPA), the Office of Water (OW) publishes test procedures (analytical methods) for analysis of wastewater and drinking water. Listed at parts 136 and 141 of Title 40 of the *Code of Federal Regulations* (CFR), these methods are authorized for use in data gathering and environmental monitoring under the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA). These methods have been developed by EPA, by consensus standards organizations, and by others. Many of these methods, especially methods published before 1990, are prescriptive with limited ability to modify procedures or change technologies to accommodate specific situations. There has been a growing awareness within EPA and the analytical community that the requirement to use prescriptive measurement methods and technologies to comply with Agency regulations has unintentionally imposed a significant regulatory burden and created a barrier to the use of innovative environmental monitoring technology.

EPA has demonstrated its commitment to reducing unnecessary regulatory burdens by initiating a number of programs that respond to the needs of the regulated community, the technology development community, and the laboratory services community. As part of this new Agency-wide approach, EPA's Office of Science and Technology (OST) and Office of Ground Water and Drinking Water (OGWDW) have coordinated with various Headquarters offices, EPA Regions, States, other governmental agencies, water and wastewater utilities, industry, environmental laboratories, instrument vendors, consensus standards organizations, and other interested parties to define a comprehensive program to streamline OW's water test methods approval program. The streamlining initiative encourages the use of emerging and innovative technologies by (1) increasing method flexibility so that approved methods can be modified without formal EPA approval, (2) providing a mechanism for non-EPA organizations to develop and submit new methods for approval, and (3) expediting the method approval process. EPA believes that streamlining also offers the opportunity to improve the quality of environmental monitoring.

The streamlining initiative seeks to allow laboratories and regulated entities to use professional judgement in modifying and developing alternatives to approved test methods to take advantage of emerging technologies that reduce costs, overcome analytical difficulties, and enhance data quality. A necessary condition of method flexibility is the requirement that a modified method produce results equivalent or superior to results produced by the approved reference method. EPA believes that increasing method flexibility and streamlining the method approval process will provide several benefits. Permittees, permit writers, public water systems, and drinking water laboratories will be allowed the flexibility to select the analytical method that yields improved performance in specific discharge or drinking water monitoring situations. The flexibility to select more appropriate methods provides an opportunity to use new technologies to overcome matrix interference problems, lower

detection limits, improve laboratory productivity, or reduce the amount of hazardous wastes in the laboratory.

A more flexible method approval program is consistent with President Clinton's Environmental Technology and Reinventing Government initiatives and Congress' National Technology Transfer and Advancement Act of 1995 (NTTAA). It will empower stakeholders while decreasing demands on Agency resources. The streamlined program is intended to accelerate environmental technological innovation as a means of strengthening America's economy and creating jobs while enhancing environmental protection. EPA believes that the incentives provided by a more flexible water test methods approval program will spur the development of new technologies and with it, new jobs. In addition, EPA anticipates that the use of new technologies may lower the cost of environmental measurements, thereby reducing costs of environmental compliance for American industries and municipalities.

1.1.1 Statutory Authority

1.1.1.1 Clean Water Act requirements

The CWA requires the EPA Administrator to promulgate effluent limitations guidelines for specified categories and classes of point sources. Section 301 of the CWA prohibits the discharge of any pollutant into navigable waters unless the discharge complies with a National Pollutant Discharge Elimination System (NPDES) permit issued under Section 402 of the Act. Section 307 requires the EPA Administrator to publish regulations establishing pretreatment standards for introduction of pollutants into publicly owned treatment works (POTWs). Section 401 requires certification for the construction or operation of facilities which may result in any discharge into the navigable waters.

CWA Section 304(h) requires the EPA Administrator to promulgate guidelines establishing test procedures for data gathering and monitoring compliance with published guidelines. EPA's approval of analytical methods is authorized under this section of CWA, as well as the general rulemaking authority in CWA Section 501(a). The Section 304(h) test procedures (analytical methods) are specified at 40 CFR part 136. They include “Methods for Chemical Analysis of Water and Waste” (MCAWW); the 600- and 1600- series methods; methods published by consensus standards organizations such as ASTM and AOAC-International, and the publication “Standard Methods for the Examination of Water and Wastewater” (Standard Methods), which is published jointly by the American Public Health Association (APHA), the American Water Works Association (AWWA), and the Water Environment Federation (WEF); methods used by the U.S. Geological Survey; methods developed by the environmental community; and other methods referenced in CWA regulations. EPA uses these test procedures to support development of effluent limitations guidelines approved at 40 CFR parts 400 - 499, to establish compliance with (NPDES) permits issued under CWA Section 402, for implementation of the pretreatment standards issued under CWA Section 307, and for CWA Section 401 certifications.

1.1.1.2 Safe Drinking Water Act requirements

The SDWA requires the EPA Administrator to promulgate national primary drinking water regulations (NPDWRs) that specify maximum contaminant levels (MCLs) or treatment techniques for listed drinking water contaminants (Section 1412). In addition, Section 1445(a) of SDWA authorizes the Administrator to establish regulations for monitoring to assist in determining whether persons are acting in compliance with the requirements of SDWA. EPA's approval of analytical test procedures is

authorized under these sections of SDWA, as well as the general rulemaking authority in SDWA Section 1450(a).

SDWA Section 1401(1)(D) specifies that NPDWRs contain criteria and procedures to ensure a supply of drinking water that dependably complies with MCLs, including quality control (QC) and testing procedures to ensure compliance with such levels and to ensure proper operation and maintenance of drinking water supply and distribution systems. These test procedures (analytical methods) are approved at 40 CFR part 141. They include MCAWW methods; the 200, 300 and 500 series methods; and other methods referenced in SDWA regulations. EPA uses these test procedures to establish MCLs under SDWA Section 1412 and to establish monitoring requirements under SDWA Section 1445(a).

1.1.2 Current Office of Water Methods Approval Programs

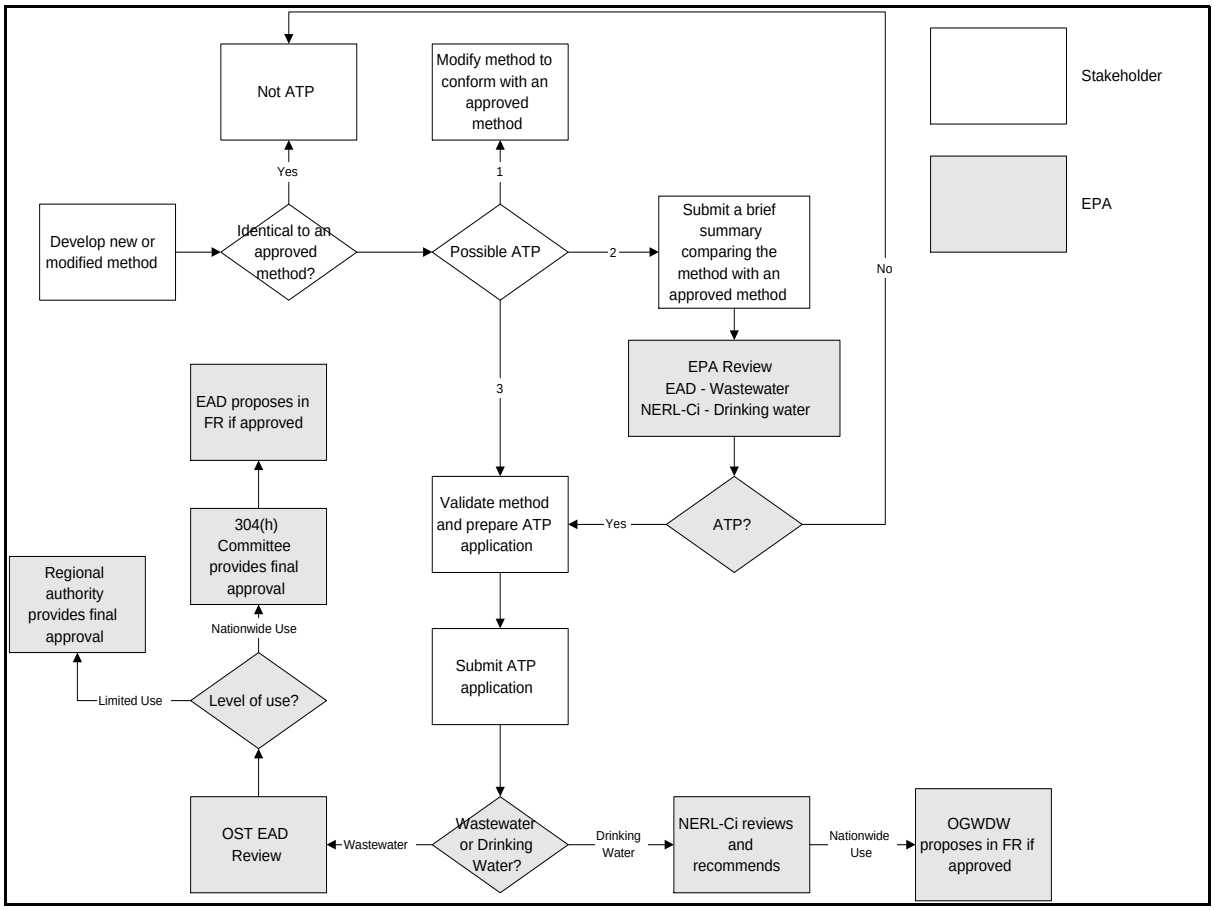
Requirements for approval of alternate analytical techniques (methods) are specified at 40 CFR 136.4 and 136.5 for wastewater methods and at 40 CFR 141.27 for drinking water methods. These requirements are the basis for the Agency's alternate test procedure (ATP) program for water methods. Under the ATP program, an organization may submit an application for approval of a modified version of an approved method or for approval of a new method to be used as an alternate to an approved method. The submitting organization is responsible for validating the new or modified method. The Agency reviews the ATP validation package and, if required, promulgates successful applications in the CFR. Rulemaking is required when a new or revised method is added to the list of approved methods in the CFR. The ATP and rulemaking processes make heavy demands on stakeholder, contractor, EPA, and *Federal Register* resources. These processes can require several months to approve a minor method modification and a year or more to promulgate a major modification or a new technology. Because advances in analytical technology continue to outpace the capacity of OW's method approval program, the program has been under-utilized and slow to respond to emerging technologies. In the streamlining initiative, which is described below, EPA proposes to amend the procedures at 40 CFR 136.4, 136.5, and 141.27 to specify a more rapid and less resource intensive process for approval of new technologies. The current ATP process is depicted in **Figure 1.1.**

1.2 The Streamlining Initiative

Upon accepting responsibility for the wastewater methods approval program, EPA's EAD undertook a review of the method needs and available resources of EPA; the regulated community; state, regional, and local permitting authorities; and the analytical services community. EAD determined that the methods approval program would best be served by undertaking a streamlining initiative to (1) expand the flexibility to modify approved methods without a cumbersome review and approval process, in order to allow timely introduction of emerging technologies; and (2) expedite the approval of new and modified methods, involving outside organizations in the method development process. During 1995 and 1996, EAD developed and refined a comprehensive initiative to streamline OW's method approval program. This streamlining initiative is a combined effort of EPA's Office of Science and Technology and Office of Ground Water and Drinking Water and applies to approval of wastewater and drinking water methods.

To keep pace with advances in technology, EPA believes that this is an appropriate time to look to organizations outside of EPA to assist in the development of new methods and to find ways to take advantage of emerging technologies to reduce costs, overcome interferences, and enhance data quality. Once the streamlining initiative is in place, EPA expects to increase its reliance on outside

Figure 1-1: The Current Alternate Test Procedure Process



organizations to develop new methods. EPA will focus its methods development efforts on specialized, esoteric, or orphan methods to support regulation development or compliance monitoring.

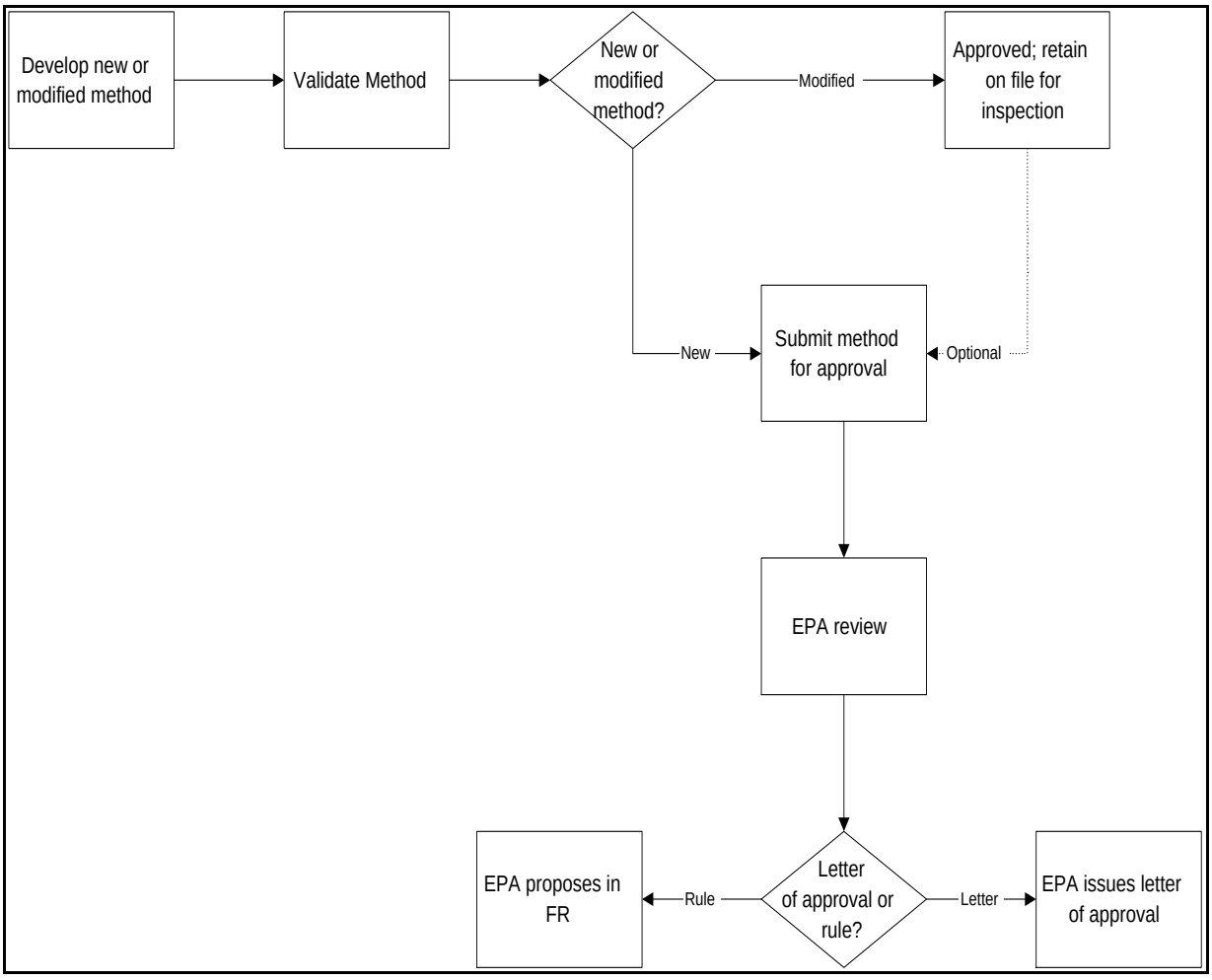
EPA recognizes that expanded flexibility must be matched with controls to ensure that program quality is maintained. These controls include a system for organizations that modify methods to demonstrate and document equivalency of the modified method to the approved reference method. The requirements for documenting equivalency of modified methods are tiered to reflect the variety of conditions under which a modification will be applied. The requirements for validating newly developed methods are similarly tiered.

An overview of the proposed streamlined method approval program described in this Guide is depicted in **Figure 1.2**. This streamlined program would replace the current ATP process depicted in Figure 1.1.

1.2.1 Streamlining Objectives

The proposed streamlining initiative is designed to improve overall resource use while making the method development process more efficient and accessible to non-EPA organizations. The goals

Figure 1-2: Proposed Streamlined Methods Approval Program



of the initiative are to decrease the need for developers of modified methods to use the ATP program and to speedup the approval (or disapproval) of methods subject to ATP review. EPA has defined several specific objectives to meet these goals. The objectives of the streamlining initiative are to:

(1) Increase the current flexibility to modify approved chemical and biological test methods without formal EPA approval; this will allow laboratories to overcome matrix interferences and will facilitate early introduction of innovative technologies.

(2) Designate a reference method for each combination of analyte and determinative technique and establish standardized quality control (QC) tests for approved methods, to ensure data quality while allowing for method flexibility.

(3) Develop QC acceptance criteria for reference methods lacking these criteria, to provide a means whereby a laboratory can demonstrate equivalent or superior performance of a modified method.

(4) Provide a standard mechanism for validation and approval of new chemical and biological test methods, including a standard method format, to expedite method approval and increase confidence in the validity of the methods and resulting data.

(5) Encourage stakeholder participation in method development, to keep pace with emerging technologies.

(6) Prepare to harmonize the wastewater and drinking water methods by setting the stage for consolidation of the water methods.

(7) Increase standardized data reporting by recommending use of standard data elements for reporting analytical results for environmental and QC samples.

(8) Identify and propose withdrawal of outdated methods from 40 CFR parts 136 and 141, to modernize approved test methods.

1.2.2 Benefits of Streamlining

Advantages of streamlining EPA's water methods approval program are expected to be widely shared by EPA, purveyors of new technology, the regulated community, regulatory authorities, and analytical laboratories. Flexibility in methods is expected to enhance compliance monitoring programs by reducing the need for EPA and state, regional, and local permitting authorities to review and provide formal approval of specific method adaptations. In addition, method flexibility, along with a well-defined program for developing and approving new methods, will provide research laboratories, instrument vendors, and equipment manufacturers with incentives for developing new analytical techniques. This, in turn, will provide the regulated community and their laboratories more flexibility to select analytical methods that yield improved performance in specific wastewater discharge or drinking water monitoring situations.

Expanding method flexibility and streamlining the method approval process will yield several benefits.

(1) Because of increased flexibility to modify methods without formal EPA approval, only new methods require formal EPA approval. Because ATPs for modified methods will be processed only upon request, the number of methods that must pass through the rulemaking process will be significantly reduced. This will reduce demand on Agency resources at the same time that the use of new technologies accelerates.

(2) Allowing more extensive modification of existing methods will make laboratory operations more efficient, reduce analytical costs, reduce the amount of hazardous materials in laboratories, enhance development of new instrumentation, and improve the quality of environmental data.

(3) Non-EPA organizations, including instrument vendors and laboratories, will have a mechanism for gaining timely approval of new methods

(4) Use of direct final rulemaking for approval of noncontroversial method revisions will decrease the time and effort to approve and list a method in the CFR.

(5) Detailed guidance on the preparation and submission of requests for approval of new methods will ensure that new methods are approved as quickly as possible.

(6) Requirements for standard QC tests in all methods will ensure consistency among methods and enhance program and data quality.

(7) Established method validation requirements will facilitate method development as well as ensuring that, prior to approval, all methods undergo levels of testing appropriate to their intended use.

1.2.3 Development of EPA's Streamlining Initiative

Between April and August 1995, EPA developed a “straw man” for streamlining, composed of several draft documents dealing with issues of method flexibility, standardized QC, method validation, and method format. This straw man was provided to and discussed with participants at several public meetings on streamlining held by EPA. As of the publication date of this draft guide, EPA has conducted four public meetings on streamlining its water test methods approval program. These meetings were held in Seattle, Washington on September 28, 1995; Boston, Massachusetts on January 25, 1996; Chicago, Illinois on February 14, 1996; and Denver, Colorado on July 24, 1996. The purpose of these meetings was to present and discuss EPA's straw man for streamlining and to obtain stakeholder suggestions for the purpose of refining the streamlining approach prior to its proposal.

All meetings were announced in the *Federal Register* in advance. The first meeting, held in Seattle, was announced on September 12, 1995, in a *Federal Register* notice titled, "A Public Meeting and Availability of Documents on Streamlining Approval of Analytical Methods at 40 CFR Part 136 and Flexibility in Existing Test Methods" (60 *FR* 47325). That *Federal Register* notice provided supplementary information regarding the streamlining effort and made available several supporting documents. Subsequent public meetings in Boston and Chicago were announced in a *Federal Register* notice dated December 18, 1995 (60 *FR* 65206), and the fourth public meeting in Denver was announced in a *Federal Register* notice on July 10, 1996 (61 *FR* 36328).

Stakeholder comments at the public meetings showed strong support for all of the streamlining objectives. The straw man and summaries of the public meetings were distributed to meeting participants and made available to others in response to requests through OST. Following the first three public meetings, EPA compiled and reviewed preliminary stakeholder advice to assess the initial response to streamlining and revise the approach accordingly. In response to stakeholder suggestions, EPA added seven items to the streamlining initiative:

- Drinking water methods (40 CFR part 141) were included.
- Flexibility was expanded to include changes to the determinative technique.
- Flexibility was qualified to clarify that flexibility in front-end techniques does not apply to sample collection and preservation.
- Tier 1 validation was expanded to allow single-laboratory application of a method modification to multiple matrix types.
- An option to have EPA review Tier 2 and Tier 3 method modifications, upon request, was added.
- An option to have EPA propose and promulgate reviewed Tier 2 and Tier 3 method modifications, upon request, was added.
- An option to submit screening methods for approval as new methods was added.

This Streamlining Guide and the *Guidelines and Format for Methods to be Proposed at 40 CFR Part 136 or Part 141* (Method Guidelines and Format) were developed in July 1996, and replaced the supplementary information made available through the September 12, 1995, notice. These documents served as the new straw man discussed at the final public meeting on streamlining held in Denver.

In addition to the public meetings, EPA solicited support and expertise from each of the consensus standards organizations and government agencies that have developed methods already approved for use under the wastewater and drinking water programs. These groups include the American Public Health Association (APHA), American Water Works Association (AWWA), and Water Environment Federation (WEF) as publishers of Standard Methods for the Examination of Water and Wastewater (Standard Methods); ASTM (formerly, American Society for Testing and Materials); AOAC-International (formerly the Association of Official Analytical Chemists); and the U.S. Geological Survey (USGS). EPA also provided the opportunity for individuals, the regulated industry, vendors, laboratories, and laboratory organizations such as the International Association of Environmental Testing Laboratories (IAETL) to voice opinions at these meetings. These groups offered valuable insight concerning problems with the current program and recommended areas of improvement. Also, some of these organizations have developed or are developing standardized procedures for the areas listed above. In these instances, EPA has built upon the experience and efforts of these organizations. For example, EPA recommends use of the method validation protocols developed by ASTM and AOAC-International.

Major stakeholder organizations have participated in and provided input at the public meetings. These organizations include: International Association for Environmental Testing Laboratories American Association for Laboratory Accreditation, American Chemical Society, American Council of Independent Laboratories, American Industrial Hygiene Association, American Water Works Association, Chemical Manufacturers Association, and Water Environment Federation.

To ensure that the streamlining initiative remains current and is responsive to changing policies, OW has committed to support committees such as the Environmental Monitoring Management Council (EMMC) and the National Environmental Laboratory Accreditation Committee (NELAC). OW also is committed to tracking method development efforts by stakeholders such as ASTM, AOAC-International, and the National Council of the Paper Industry for Air and Stream Improvement (NCASI).

EPA has used informal suggestions received at public meetings and through unsolicited correspondence in developing its approach to streamlining that is described in this guide. Formal comments on the streamlining initiative will be requested when streamlining is proposed in the *Federal Register*.

1.2.4 Implementation Issues

Through the public meetings and stakeholder discussions, EPA has identified and is addressing key implementation issues related to streamlining.

1.2.4.1 Legal issues

Stakeholders expressed concern regarding potential conflicts between regulators and regulated entities when using modified methods. For example, there was wide-spread concern over what would happen if a discharger used a modified method and demonstrated compliance with a regulatory concentration limit whereas a regulatory authority used the unmodified reference method and obtained results suggesting that the discharger was out of compliance.

Representatives from EPA's OST, Office of Wastewater Management, and Office of Enforcement and compliance Assurance met to study this question. Through these discussions it became apparent that the streamlined program would work only if the modified method, once demonstrated to be equivalent to the reference method, carried the same legal force and effect as the reference method. Therefore, the difference in results produced by the modified and unmodified reference methods would be attributable not to the modification, but to differences in results produced by two laboratories. This situation is no different than the situation that currently exists, in that two laboratories can produce different results, one of which is above and the other below a regulatory compliance limit. The legal resolution would therefore remain the same as today -- a decision would be made based on examination of the data.

1.2.4.2 Resource issues

Drinking water laboratory certification officials and pretreatment coordinators have expressed a common concern regarding the expertise and resources needed to adequately assess documentation of method equivalency when modifications are used. To help alleviate this concern, EPA is providing detailed guidance and checklists for assessing method modifications for equivalency with a reference method (see Chapter 6). EPA also may provide training and other types of assistance in this area.

1.2.4.3 The alternate test procedure process

OW anticipates that the flexibility allowed under streamlining will greatly reduce the number of ATPs processed. The ATP process will remain in place as an option to be used for modified methods that are approved and listed in the CFR. Expedited approval procedures, including use of direct final rulemaking for noncontroversial actions, will significantly decrease the time required for approval a method that has received a favorable recommendation from EPA.

1.2.4.4 Pilot testing

OW plans to pilot test the streamlining program prior to implementation. The pilot tests will focus on (1) method flexibility and (2) development and approval of new methods. EPA anticipates conducting several case studies in each of these areas during 1997. The pilot test reports will be reviewed and assessed for changes that should be made to the streamlining program before nationwide implementation.

1.2.4.5 Concerns by consensus standards organizations

Many of the methods approved at 40 CFR parts 136 and 141 are methods developed by consensus standard organizations such as Standard Methods, ASTM, and AOAC-International. In designating reference methods for specific combinations of analytes and determinative techniques, it was EPA’s intent to select as the reference method, the method that contained QC acceptance criteria for the standard QC elements identified in the streamlining initiative, regardless of whether that method was an EPA method or one developed by another organization.

As envisioned, the streamlining initiative allows modification to the reference method, provided that the QC acceptance criteria are met. Consensus standards organizations have expressed concern that modification of their methods would constitute a legal violation of the method, termed a "standard". Therefore, Standard Methods, ASTM, and AOAC-International have declined to allow any modifications to their designated methods that are not expressly permitted in the methods. Hence, their methods cannot be modified under the procedures outlined in this document and cannot be specified as reference methods in 40 CFR part 136 or 141. This restriction will be noted in the specification of these methods in the CFR tables.

This restriction does not greatly impact the streamlining initiative, because an EPA method exists that can be used as a reference method for nearly all analytes, and because most methods from consensus standards organizations have sufficient explicit internal flexibility to meet the objectives of streamlining and are frequently updated to reflect recent advances in technology. EPA expects to continue relying on consensus standards organizations for the development of future methods as required by the NTTAA and because of limited Agency resources for method development.

1.3 Purpose of Guide

The purpose of this document is to provide detailed guidance to permittees, water utilities, regulatory authorities, purveyors of new technology, and analytical laboratories on implementation of a comprehensive program to expand flexibility and streamline approval of methods under EPA's wastewater and drinking water programs.

1.4 Content and Organization of Guide

The remainder of this document outlines the framework of and provides detailed guidance on EPA's streamlining initiative. Some chapters are procedural and others are descriptive, as appropriate to the topic.

- **Chapter 2 - Method Flexibility**
  This chapter describes the extent of existing method flexibility and outlines the principal concepts of the expanded flexibility that EPA proposes to allow in order to implement a performance-based approach to approving compliance methods in the Office of Water.

- **Chapter 3 - Quality Control Requirements**
  This chapter describes the standard quality control tests that will be required for all methods and specifies procedures for developing performance (i.e. QC acceptance criteria) for new methods.

- **Chapter 4 - Method Validation Requirements**
  This chapter describes the requirements and procedures for validating and documenting validation of a new method or method modification, utilizing a tiered system based on the intended application of the method.

- **Chapter 5 - The Method Approval Process**
  This chapter describes the expedited method approval process that includes a standard method format and procedures for submitting validated methods to EPA for approval.

- **Chapter 6 - Assessing Method Equivalency**

This chapter provides guidance for assessing whether a method modification produces results equivalent to results produced by a reference method.

- **Chapter 7 - Biological Method Issues**
  The final chapter describes possible future plans to extend flexibility to biological methods. Biological methods include measurement of microbiological parameters as well as methods with biological indicators of toxicity.

The Guide includes several Appendices that contain useful reference materials.

- **Appendix A** provides a comprehensive list of acronyms and abbreviations used in the Guide.
- **Appendix B** is a glossary of terms used in the Guide.
- **Appendix C** contains descriptions of method modifications to 600- and 1600-series EPA methods that have been determined to be within the currently allowed flexibility described in Chapter 2.
- **Appendix D** comprises a list of suggested data elements for reporting, as discussed in Chapter 4.
- **Appendix E** provides the EMMC checklists and certification statement that serve as the basis for proving and evaluating method equivalency, as described in Chapter 6. It also provides an example of a completed method equivalency checklist.
- **Appendix F** specifies QC acceptance criteria for approved inorganic methods that are proposed as reference methods and that do not contain QC acceptance criteria.
- **Appendix G** lists the bibliographic references used in the development of the Guide.